UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION
PREVENTION

July 19, 2012

MEMORANDUM

SUBJECT: Efficacy Review for GIRAFFE;
EPA Reg. No. 4822-LIO;
DP Barcode: D401056

FROM: Karen M. Hill, Ph.D.
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THRU: Tajah Blackburn, Ph.D.
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7/26/12

TO: Marshall Swindell RM33/ Zebora Johnson
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: S.C. Johnson & Son, Inc.
1525 Howe Street
Racine, Wisconsin 53403

Formulation from the Label:

Active Ingredient(s):	% by wt.
Hydrogen peroxide.....	0.77%
Inert Ingredients.....	99.23%
Total.....	100.00%

I. BACKGROUND:

The product, Giraffe (EPA Reg. No. 4822-LIO), is seeking registration as a new end use product with disinfectant (bactericidal and virucidal activity) and sanitizing claims for use on hard, non-porous surfaces in institutional, industrial, and residential environments. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121. The studies submitted in application for the registration of product Giraffe are bridged from the application of the identical parent product Glass Spray from Aseptix Research BV Company (EPA Reg. No. 89094-U). A background document was submitted with the application that states the identical nature of the two products and each product label.

This data package contained a letter dated March 1, 2012 from the applicants agent to EPA (MRID # 487701-00), seven studies (MRID 487701-03 thru 487701-09), a Data Matrix (EPA form 8570-35), a Confidential Statement of Formula (EPA form 8570-4), Statements of No Data Confidentiality Claims for all studies, and the proposed label.

II. USE DIRECTIONS:

The product is designed for disinfecting and sanitizing hard non-porous surfaces including countertops, oven doors, microwaves exterior, range tops, range hoods, vinyl siding, floors, walls, sinks, showers, handrails, high chairs, hubcaps, garbage cans, tubs, washing machines, mirrors, plastic (patio) furniture, refrigerator exterior, shower doors, telephones, tires, lamp, lap tops, grills, window blinds, ceiling fans, cell phones, cribs, cutting boards, drains, dishwasher, faucets, furniture, exercise equipment, China, China cabinet, cabinets, changing tables, light fixtures, mudrooms, toilet (handles) (seat) (rim) (tank), glass, computer screens, range hood, range tops, artificial plants, baseboards, molding, trim, automobile interior (dash, seats, windows, windshield), automobile shops, bathroom surfaces, bicycles, boats, bookcase, pianos, pictures, remote controls, shower heads, diaper pails, dish racks, door knobs, glazed bathroom tiles, glazed ceramic tile, glazed porcelain surfaces, glazed procelain, linoleum, metal, polystyrene, sealed fiberglass, sealed synthetic marble, stainless steel, vinyl, and chrome. Directions on the proposed label provide the following information regarding use of the product on hard non-porous surfaces:

To disinfect: Spray surface until thoroughly wet. Allow surface to remain wet for 5 minutes and then wipe. For heavily soiled areas, a precleaning is required. Rinse with potable water for food-contact surfaces.

To sanitize: Spray surface until thoroughly wet. All surface to remain wet for 30 seconds and then wipe. For heavily soiled areas, a precleaning is required. Rinse with potable water for food-contact surfaces.

To Control, Inhibit, or Prevent Mold and Mildew: Spray surface until thoroughly wet and allow to sit on surface for at least 5 minutes. Retreat as necessary.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS:

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments:
The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products), or the AOAC Hard Surface Carrier Test. The tests require that sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against *Salmonella enterica* ATCC 10708 (for effectiveness against Gram-negative bacteria), *Staphylococcus aureus* ATCC 6538 (for effectiveness against Gram-positive bacteria), and *Pseudomonas aeruginosa* ATCC 15442 (representative of a nosocomial pathogen). To support products labeled as "disinfectants", killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level. To pass performance requirements when using AOAC Hard Surface Carrier Test, tests must result in killing in 58 out of each set of 60 carriers for *Salmonella enterica* ATCC 10708 and *Staphylococcus aureus* ATCC 6538; 57 out of each set of 60 carriers for *Pseudomonas aeruginosa* ATCC 15442.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria):
Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10^4 microorganisms survived the carrier-drying step.

Virucides:
The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Sanitizer Test (for inanimate, non-food contact surfaces):
The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). The ASTM method states that the inoculum employed should provide a count of at least 7.5×10^5 colony forming units per carrier. Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi):
The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. Ten carriers on each of 2 product samples representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Supplemental Claims:
An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV. COMMENTS ON THE SUBMITTED EFFICACY STUDIES:

1. MRID 487701-03 "AOAC Germicidal Spray Method", Test Organisms: *Salmonella enterica* (ATCC 10708), and *Staphylococcus aureus* (ATCC 6538), for Glass Spray, Study Director Jill Ruhme. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121. Study completion date – January 05, 2012. Study Identification Number A11634.

The study was conducted against *Salmonella enterica* (ATCC 10708) *Staphylococcus aureus* (ATCC 6538). Three lots of the product were tested (Lot GS-A-LCL, Lot GS-UA-LCL-1, and Lot GS-UA-LCL2) using the provided ATS Labs protocol LEH15041311.GS.4. Lot GS-A-LCL was ≥ 60 days aged. The product was received as a ready to use trigger spray. According to the provided Confidential Statement of Formula the active ingredient lower certified limit is 0.693% and testing was done at 0.73% for Lot GS-A-LCL, 0.72% for Lot GS-US-LCL-1, and 0.71% for Lot GS-UA-LCL2. The test organisms were prepared by inoculating 10 mL of nutrient broth from a stock slant and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions of the culture were removed from the 48 - 54 hours cultures of the test system after vortex and settling of ≥10 minutes occurred. A soil load of 5% fetal bovine serum was added. Glass slide carriers (18 mm x 36 mm) were inoculated with 10 µL of the 48 - 54 hours old suspension of test organism using a pipettor and uniformly spread over the entire carrier slide. Testing was performed on different dates. For *Staphylococcus aureus* on test date June 27, 2011,

the carriers were dried for 40 ± 2 minutes at 35-37°C with 40% relative humidity. For *Salmonella enterica* on test date June 27, 2011, the carriers were dried for 30 - 40 minutes at 35-37°C with 60% relative humidity. For *Staphylococcus aureus* on test date July 20, 2011, the carriers were dried for 40 ± 2 minutes at 35-37°C with 51% relative humidity. For *Salmonella enterica* on test date July 20, 2011, the carriers were dried for 30 - 40 minutes at 35-37°C with 51% relative humidity. Each carrier in a horizontal position was sprayed with the product using 3 sprays at a distance of 4 - 6 inches from the carrier surface. For testing performed on June 27, 2011, each carrier remained in contact with the product for 5 minutes at 21°C with 50% relative humidity. For testing performed on July 20, 2011, each carrier remained in contact with the product for 5 minutes at 21°C with 64% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth with 0.1% Sodium Thiosulfate to neutralize. All subcultures were incubated for 48 ± 2 hours at 35 - 37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Confidential Statement of Formula (CSF) contains a note to the reviewer addressing the tested active ingredient concentration.

2. MRID 487701-04 "AOAC Germicidal Spray Method", Test Organisms: *Pseudomonas aeruginosa* (ATCC 15442), for Glass Spray, Study Director Joshua Luedtke. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121. Study completion date – January 26, 2012. Study Identification Number A12545.

The study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Three lots of the product were tested (Lot GS-A-LCL, Lot GS-UA-LCL-1, and Lot GS-UA-LCL2) using the provided ATS Labs protocol JW01122111.GS.5. Lot GS-A-LCL was ≥ 60 days aged. The product was received as a ready to use trigger spray. According to the provided Confidential Statement of Formula the active ingredient lower certified limit is 0.693% and testing was done at 0.72% for Lot GS-US-LCL-1, and 0.71% for Lot GS-UA-LCL2. The test organism was prepared by inoculating 10 mL of nutrient broth from a stock slant and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. On the day of use, the pellicle was aspirated from the *Pseudomonas aeruginosa* culture and the remaining culture was aseptically removed by tilting each tube to allow any remaining pellicle to slide back and away while aspirating the culture. Afterwards, the culture was transferred to a sterile tube. The upper portions of the culture were removed from the 48 - 54 hours cultures of the test system after vortex and settling of ≥10 minutes occurred. A soil load of 5% fetal bovine serum was added. Glass slide carriers (18 mm x 36 mm) were inoculated with 10 µL of the 48 - 54 hours old suspension of test organism using a pipettor and uniformly spread over the entire carrier slide. The carriers were allowed to dry for 38 minutes at 35 – 37°C with 40% relative humidity. Each carrier in a horizontal position was sprayed with the product using 4 sprays at a distance of 4 - 6 inches from the carrier surface. Each carrier remained in contact with the product for 5 minutes at 21°C with 22% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth + 0.1% Sodium Thiosulfate + 0.01% Catalase to neutralize. All subcultures were incubated for 48 ± 2 hours at 35 - 37°C.

Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Confidential Statement of Formula (CSF) contains a note to the reviewer addressing the tested active ingredient concentration.

3. MRID 487701-05 "AOAC Germicidal Spray Method", Test Organisms: *Escherichia coli* O157:H7 (ATCC 35150), for Glass Spray, Study Director Matthew Sathe. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121. Study completion date – February 2, 2012. Study Identification Number A12583.

The study was conducted against *Escherichia coli* O157:H7 (ATCC 35150). Two lots of the product were tested (Lot GS-UA-LCL-1, and Lot GS-UA-LCL2) using the provided ATS Labs protocol JW01122111.GS.4. The product was received as a ready to use trigger spray. According to the provided Confidential Statement of Formula the active ingredient lower certified limit is 0.693% and testing was done at 0.72% for Lot GS-US-LCL-1, and 0.71% for Lot GS-UA-LCL2. The test organism was prepared by inoculating 10 mL of nutrient broth from a stock slant and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions of the culture were removed from the 48 - 54 hours cultures of the test system after vortex and settling of ≥10 minutes occurred. A soil load of 5% fetal bovine serum was added. Prior to inoculation, the carriers were equilibrated under the dying conditions for approximately 20 minutes. Afterwards, the glass slide carriers (18 mm x 36 mm) were inoculated with 10 µL of the 48 - 54 hours old suspension of test organism using a pipettor and uniformly spread over the entire carrier slide. The carriers were allowed to dry for 30 minutes at 35 – 37°C with 50% relative humidity. Each carrier in a horizontal position was sprayed with the product using 4 sprays at a distance of 4 - 6 inches from the carrier surface. Each carrier remained in contact with the product for 5 minutes at 23.1°C with 9.4% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth + 0.1% Sodium Thiosulfate + 0.01% Catalase to neutralize. All subcultures were incubated for 48 ± 2 hours at 35 - 37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note- A protocol deviation was noted in the study. Prior to inoculation all carriers were equilibrated under the drying conditions for approximately 20 minutes which is a deviation from standard protocol.

Note: Confidential Statement of Formula (CSF) contains a note to the reviewer addressing the tested active ingredient concentration.

4. MRID 487701-06 "AOAC Germicidal Spray Method", Test Organisms: Streptococcus pyogenes (ATCC 19615), for Glass Spray, Study Director Matthew Sathe. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121. Study completion date – February 15, 2012. Study Identification Number A12573.

The study was conducted against *Streptococcus pyogenes* (ATCC 19615). Two lots of the product were tested (Lot GS-UA-LCL-1, and Lot GS-UA-LCL2) using the provided ATS Labs protocol JW01122111.GS.3. The product was received as a ready to use trigger spray. According to the provided Confidential Statement of Formula the active ingredient lower certified limit is 0.693% and testing was done at 0.72% for Lot GS-US-LCL-1, and 0.71% for Lot GS-UA-LCL2. The test organism was prepared by inoculation of multiple agar plates and incubation of inoculated plates for 3 days at 35 – 37°C on CO_2. Afterwards, the organism was suspended in Fluid Thioglycollate media. A soil load of 5% fetal bovine serum was added. Glass slide carriers (18 mm x 36 mm) were inoculated with 10 µL of the test organism suspension using a pipettor and uniformly spread over the entire carrier slide. The carriers were allowed to dry for 30 minutes at 25 – 30°C with 65% relative humidity. Each carrier in a horizontal position was sprayed with the product using 4 sprays until thoroughly wet at a distance of 4 - 6 inches from the carrier surface. Each carrier remained in contact with the product for 5 minutes at 20°C with 22% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Brain Heart Infusion Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.01% Catalase to neutralize. All subcultures were incubated for 48 ± 2 hours at 35 - 37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note- The protocol was amended to compensate for population control failure and the test was repeated with the change in the preparation of test organism using growth media Tryptic Soy Agar + 5% Sheep's Blood in place of Brain Heart Infusion Broth.

Note: Confidential Statement of Formula (CSF) contains a note to the reviewer addressing the tested active ingredient concentration.

5. MRID 487701-07 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: Influenza A (H1N1) Virus (ATCC VR- 1469), for Glass Spray, Study Director Shanen Conway. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121. Study completion date – February 27, 2012. Study Identification Number A12603.

The study was conducted against A/PR/8/34 strain of Influenza A (H1N1) virus (ATCC VR-1469). Rhesus monkey kidney (RMK) cells (obtained from ViroMed Laboratories, Inc., Cell Culture Division) were used as the host cell line. Three lots of the product were tested (Lot GS-A-LCL, Lot GS-UA-LCL-1, and Lot GS-UA-LCL2) using the provided ATS Labs protocol JW01122111.FLUA.1. Lot GS-A-LCL was ≥ 60 days aged. The product was received as a ready to use trigger spray. According to the provided Confidential Statement of Formula the active ingredient lower certified limit is 0.693% and testing was done at 0.73% for Lot GS-A-LCL, 0.72% for Lot GS-US-LCL-1, and 0.71% for Lot GS-UA-LCL2. The stock virus was prepared by collecting supernatant fluid

from disrupted 75 – 100% infected cultured cells in which the cell debris was separated and removed from the supernatant by centrifugation. The supernatant culture fluid was removed, aliquoted, and the high titer stock virus was stored at ≤ - 70°C until the day of use. On the day of use, an aliquot of stock virus (ATS Labs Lot FLUA-29) was thawed and maintained at a refrigerated temperature until use in the assay. The virus culture was adjusted to contain a soil load of 5% fetal bovine serum. Virus films were prepared by inoculating 200 µL and spreading it uniformly over the bottoms of twenty (20) separate 100 mm X 15 mm sterile glass Petri dishes. The virus films were dried for 20 minutes at 20°C with 40% relative humidity. Each carrier was sprayed with the product for 3 sprays until thoroughly wet at a distance of 4 – 6 inches from the carrier surface. Each carrier remained in contact with the product for 5 minutes at 22°C. Following exposure, the plates were scraped and the resuspended contents were passed through individual Sephadex columns. The filtrates were then diluted serially 10-fold and assayed for infectivity and cytotoxicity. RMK cells in multiwell culture dishes were inoculated with 100 µL of the test substance prepared dilutions in quadruplicate. The cultures were incubated at 36 – 38°C with 5 – 7% CO_2 and scored periodically for seven days for the presence or absence of CPE, cytotoxicity, and for viability. Controls included those for viability, input virus control, dried virus control, cytotoxicity control, and neutralization confirmation. The calculation of titers was performed using the Spearman and Karber method.

Note: Confidential Statement of Formula (CSF) contains a note to the reviewer addressing the tested active ingredient concentration.

6. MRID 487701-08 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: Respiratory Syncytial virus (ATCC VR- 26), for Glass Spray, Study Director Mary J. Miller. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121. Study completion date – February 7, 2012. Study Identification Number A12590.

The study was conducted against Long strain of Respiratory Syncytial virus (ATCC VR-26). Human larynx carcinoma (Hep-2) cells (obtained from ViroMed Laboratories, Inc., Cell Culture Division) were used as the host cell line. Three lots of the product were tested (Lot GS-A-LCL, Lot GS-UA-LCL-1, and Lot GS-UA-LCL2) using the provided ATS Labs protocol JW01122111.RSV.2. Lot GS-A-LCL was ≥ 60 days aged. The product was received as a ready to use trigger spray. According to the provided Confidential Statement of Formula the active ingredient lower certified limit is 0.693% and testing was done at 0.73% for Lot GS-A-LCL, 0.72% for Lot GS-US-LCL-1, and 0.71% for Lot GS-UA-LCL2. The stock virus was prepared by collecting supernatant fluid from disrupted 75 – 100% infected cultured cells in which the cell debris was separated and removed from the supernatant by centrifugation. The supernatant culture fluid was removed, aliquoted, and the high titer stock virus was stored at ≤ - 70°C until the day of use. On the day of use, an aliquot of stock virus (ATS Labs Lot NRSV-24) was thawed and maintained at a refrigerated temperature until use in the assay. The virus culture was adjusted to contain a soil load of 5% fetal bovine serum. Virus films were prepared by inoculating 200 µL and spreading it uniformly over the bottoms of twenty (20) separate 100 mm X 15 mm sterile glass Petri dishes. The virus films were dried for 20 minutes at 20°C with 50% relative humidity. Each carrier was sprayed with the product for 3 sprays until thoroughly wet at a distance of 4 – 6 inches from the carrier surface.

Each carrier remained in contact with the product for 5 minutes at 22°C. Following exposure, the plates were scraped and the resuspended contents were passed through individual Sephadex columns. The filtrates were then diluted serially 10-fold and assayed for infectivity and cytotoxicity. Hep-2 cells in multiwell culture dishes were inoculated with 100 µL of the test substance prepared dilutions in quadruplicate. The cultures were incubated at 36 – 38°C with 5 – 7% CO_2 and scored periodically for nine days for the presence or absence of CPE, cytotoxicity, and for viability. Controls included those for viability, input virus control, dried virus control, cytotoxicity control, and neutralization confirmation. The calculation of titers was performed using the Spearman and Karber method.

Note: Confidential Statement of Formula (CSF) contains a note to the reviewer addressing the tested active ingredient concentration.

7. MRID 487701-09 "Standard Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application)", Test Organisms: *Klebsiella pneumoniae* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538), for Glass Spray, Study Director Becky Lien. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121. Study completion date – January 25, 2012. Study Identification Number A12588.

The study was conducted against *Klebsiella pneumoniae* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538). Three lots of the product were tested (Lot GS-A-LCL, Lot GS-UA-LCL-1, and Lot GS-UA-LCL2) using the provided ATS Labs protocol JW01010512.NFS.2. Lot GS-A-LCL was ≥ 60 days aged. The product was received as a ready to use trigger spray. According to the provided Confidential Statement of Formula the active ingredient lower certified limit is 0.693% and testing was done at 0.73% for Lot GS-A-LCL, 0.72% for Lot GS-US-LCL-1, and 0.71% for Lot GS-UA-LCL2. The test organism was prepared by inoculating 10 mL of nutrient broth for *Klebsiella pneumoniae* and synthetic broth for *Staphylococcus aureus* from a stock slant and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper two-thirds of the culture were removed from the 48 - 54 hours cultures of the test system after vortex and settling of ≥15 minutes occurred. A soil load of 5% fetal bovine serum was added. Glass carriers (1" x 1") were inoculated with 20 µL of the 48 - 54 hours old suspension of test organism using a pipettor and uniformly spread to within 1/8 inch of the edges of the carrier slides. The carriers were allowed to dry for 20 minutes at 35 – 37°C with 40% relative humidity. Each carrier in a horizontal position was sprayed with the product using 3 sprays until thoroughly wet at a distance of 4 - 6 inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 21°C with 13% relative humidity. Following exposure, the carriers were transferred to 20 mL of Letheen Broth + 0.1% Sodium Thiosulfate + 0.01% Catalase to neutralize. Afterwards, the excess liquid in each Petri dish. was transferred to the neutralizer jar which contains the appropriate corresponding carrier. *S. aureus* carriers and neutralizer mixture were vortex mixed and within a 30 minutes period of neutralization duplicate 1.00 mL aliquots of neutralized solution (10^0) and of a ten-fold serial dilution (10^{-1}) was plated onto recovery agar plates. *E. aerogenes* carriers and neutralizer mixture were vortex mixed and within a 30 minutes period of neutralization duplicate 1.00 mL and 0.100 mL aliquots of neutralized solution

(10^0) were plated onto recovery agar plate medium. The plates were incubated for 48 ± 4 hours at 35 – 37°C. The subcultures were kept at 2 – 8°C for two days prior to examination. Following incubation and storage, the subcultures were visually enumerated. The controls included sterility, purity, carrier population, and neutralization confirmation.

Note: Confidential Statement of Formula (CSF) contains a note to the reviewer addressing the tested active ingredient concentration.

V. RESULTS:

Disinfectant:

MRID #	ORGANISM	RESULTS Number of Carriers with Growth/ Total Number of Carriers			Dried CFU/Carrier
		Lot GS-A-LCL	Lot GS-UA-LCL-1	Lot GS-UA-LCL2	
5 minutes contact period					
487701-03	*Salmonella enterica* Test Date: 6/27/11	---	0/60	0/60	1×10^4
487701-03	*Salmonella enterica* Test Date: 7/20/11	0/60	---	---	1.17×10^6
487701-03	*Staphylococcus aureus* Test Date: 6/27/11	---	0/60	0/60	2.69×10^6
487701-03	*Staphylococcus aureus* Test Date: 7/20/11	0/60	---	---	1.58×10^6
487701-04	*Pseudomonas aeruginosa*	0/60	0/60	0/60	1.82×10^6
487701-05	*Escherichia coli* O157:H7	---	0/10	0/10	9.1×10^4
487701-06	*Streptococcus pyogenes*	---	0/10	0/10	8.51×10^6

Virucidal:

MRID #	ORGANISM	RESULTS $TCID_{50}$/100µL			Dried Virus Control Average $TCID_{50}$/100µL
		Lot GS-A-LCL	Lot GS-UA-LCL-1	Lot GS-UA-LCL2	
5 minutes contact period					
487701-07	Influenza A (H1N1)	$\leq 10^{0.50}$ Complete killing was observed at 10^{-1} to 10^{-7} dilutions	$\leq 10^{0.50}$ Complete killing was observed at 10^{-1} to 10^{-7} dilutions	$\leq 10^{0.50}$ Complete killing was observed at 10^{-1} to 10^{-7} dilutions	$10^{5.47}$
487701-08	Respiratory Syncytial virus	$\leq 10^{0.50}$ Complete killing was observed at 10^{-1} to 10^{-6} dilutions	$\leq 10^{0.50}$ Complete killing was observed at 10^{-1} to 10^{-6} dilutions	$\leq 10^{0.50}$ Complete killing was observed at 10^{-1} to 10^{-6} dilutions	$10^{4.78}$

Non-Food Contact Sanitizer:

MRID #	ORGANISM	RESULTS			Carrier Population Mean CFU/Carrier
		Lot GS-A-LCL	Lot GS-UA-LCL-1	Lot GS-UA-LCL2	
30 seconds contact period					
487701-09	*Klebsiella pneumoniae*	$<2 \times 10^1$ Percent Reduction: >99.9%	$<2 \times 10^1$ Percent Reduction: >99.9%	$<2 \times 10^1$ Percent Reduction: >99.9%	1.4×10^7
487701-09	*Staphylococcus aureus*	$<2 \times 10^1$ Percent Reduction: >99.9%	$<2 \times 10^1$ Percent Reduction: >99.9%	$<2 \times 10^1$ Percent Reduction: >99.9%	1.26×10^7

VI. CONCLUSIONS:

1. The submitted efficacy data support the use of the product, Glass Spray, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 5% organic soil load for 5 minutes contact time:

Salmonella enterica	MRID # 487701-03
Staphylococcus aureus	MRID # 487701-03
Pseudomonas aeruginosa	MRID # 487701-04
Escherichia coli O157:H7	MRID # 487701-05
Streptococcus pyogenes	MRID # 487701-06

Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Controls were acceptable: viability controls demonstrated growth; sterility controls demonstrated no growth; neutralization effectiveness controls demonstrated neutralization.

2. The submitted efficacy data support the use of the product, Glass Spray, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 5% organic soil load for 5 minutes contact time:

Influenza A (H1N1) virus	MRID # 487701-07
Respiratory Syncytial virus	MRID # 487701-08

Complete inactivation at all tested dilutions was shown for the required number of product lots tested. No cytotoxicity was observed. Controls were acceptable: viability control demonstrated growth; sterility control did not have any growth; and neutralization effectiveness control demonstrated neutralization.

3. The submitted efficacy data support the use of the product, Glass Spray, as a sanitizer with efficacy against the following microorganisms on hard, non-porous surfaces in the presence of 5% organic soil load for 30 seconds contact time:

Klebsiella pneumoniae	MRID # 487701-09
Staphylococcus aureus	MRID # 487701-09

Results show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes (more specifically 30 seconds). The purity controls were pure. The sterility controls demonstrate no growth. Neutralization effectiveness control demonstrated neutralization.

VII. RECOMMENDATIONS:

1. The product, GIRAFFE, label claims disinfectant efficacy with bactericidal activity against the following microorganisms in the presence of 5% organic soil load for a 5 minutes contact period:

Salmonella enterica	ATCC 10708
Staphylococcus aureus	ATCC 6538
Pseudomonas aeruginosa	ATCC 15442
Escherichia coli O157:H7	ATCC 35150
Streptococcus pyogenes	ATCC 19615

These claims are **conditionally accepted**. According to the provided Confidential Statement of Formula the active ingredient lower certified limit (LCL) is 0.693% and testing was done at 0.73% for Lot GS-A-LCL, 0.72% for Lot GS-US-LCL-1, and 0.71% for Lot GS-UA-LCL2. The three lots were found to be acceptable; however the registrant must clearly define why the aged lot (Lot GS-S-LCL) has a consistently higher percentage of the active ingredient than the other two lots.

2. The product, GIRAFFE, label claims disinfectant efficacy with virucidal activity against the following microorganisms in the presence of 5% organic soil load for a 5 minutes contact period:

Influenza A (H1N1) virus	ATCC VR- 1469
Respiratory Syncytial virus	ATCC VR- 26

These claims are **acceptable** as they are supported by the submitted data.

3. The product, GIRAFFE, label claims efficacy as a non-food contact sanitizer with activity against the following microorganisms in the presence of 5% organic soil load for a 30 seconds contact period:

Klebsiella pneumoniae	ATCC 4352
Staphylococcus aureus	ATCC 6538

These claims are conditionally **accepted**. According to the provided Confidential Statement of Formula the active ingredient lower certified limit (LCL) is 0.693% and testing was done at 0.73% for Lot GS-A-LCL, 0.72% for Lot GS-US-LCL-1, and 0.71% for Lot GS-UA-LCL2. The three lots were found to be acceptable; however the registrant must clearly define why the aged lot (Lot GS-S-LCL) has a consistently higher percentage of the active ingredient than the other two lots.

4. Remove the claim "Kills MRSA* (Methicillin Resistant *Staphylococcus aureus*)" from the proposed label (Page 26). Efficacy data were not generated to support this claim.

5. On the proposed label, change *E. coli* to *E. coli* O157:H7, the tested bacterium.

6. The applicant must make the following changes to the proposed label:

- On page 2 of the proposed label and throughout the label, remove all claims and instructions related to fungicidal or mildewcidal claims. No efficacy data were submitted or approved to support these claims.
- On page 2 of the proposed label, remove the statement "Rinse with potable for food-contact surfaces" in the sanitization use direction section is unacceptable. These use instructions imply that the product is acceptable for use as a food contact sanitizer.
- Throughout the proposed label, all references to quantitative efficacy claims of 99.9% must be associated with the appropriate organism and claims (i.e. quantitative log reduction claims for disinfection are not appropriate as the disinfection test is qualitative; while 3 $\log_{10}$ reduction (99.9%) claims are appropriate for non-food contact sanitization and virucidal claims.
- On pages 3, 5, and 8 of the proposed label, the registrant must qualify all claims stating "Kills cold virus". Efficacy data are required on least two of the qualifying viruses (Rhinovirus, Coronavirus, and Respiratory Syncytial virus (RSV) to support unqualified "cold claims". When data are generated on only one of the three the cold claim must be qualified.
- On pages 4-6, the terms "oxygenated", and "will not harm surfaces" are unacceptable, as they imply safety and environmental preference.
- On pages 5, 25, and 27 of the proposed label, remove all iterations of the claim "powerful" to describe all pesticidal claims. The qualifier implies heighten efficacy.
- On page 6 of the proposed label, the claims "Cleans almost/nearly/virtually everything in your home", "any hard surface", and "works all over your home" are unacceptable as they imply that the product can be used on surfaces and sites beyond what is proposed on the label.
- On page 6 of the proposed label, the claim "gently clean almost everything" is unacceptable. This claim implies that product can be used on surfaces/sites beyond those listed and also implies safety and environmental preference.
- On pages 6 and 7 of the proposed label, the claims "Gentle/mild way to sanitize" and "Gentle for your surfaces" are unacceptable as they imply safety and environmental preference
- On page 7 of the proposed label, remove the claims "Quick sanitary action" and "fast-acting sanitary". The Agency does not have a standard for sanitary, and this term is often confused with sanitization. Should the registrant chose to replace sanitization with sanitary, the claim is still unacceptable due to the use of the terms quick (which requires contact times ≤ 10 seconds) and fast (contact time not yet defined by the Agency).
- On pages 7, 8, and 28 of the proposed label, remove the terms "gentle" and "mild" as they imply safety and environmental preference.
- On page 7 of the proposed label, the claim "Gloves off cleaning and disinfecting" is unacceptable as it implies safety and environmental preference.

- On page 8 of the proposed label, the claim "Active brakes [sic] down dirt & dissolves into oxygen into oxygen and water" is inaccurate and must be removed from the label.
- The comprehensive list of potential use sites (Table 3, pages 8-11) include the following sites that conflict with the use directions/sites and supporting efficacy claims, and should be removed from the proposed label:
    - China
    - Cutting boards
    - Can openers
    - Dish racks
    - Food preparation areas
    - Stove tops
    - Grills

- The terms ceramic, cement, fiberglass, porcelain, porcelain enamel, stone, grout, granite, marble, and wood all reflect porous surfaces in the absence of qualifying information. These surfaces must be consistently qualified or removed from the proposed label.
- On page 12 of the proposed label, use of the term "safe" is unacceptable as it is false or misleading.
- On the Table (Page 13), change the "0" to "O" for *E. coli* O157:H7.
- On page 15 of the proposed label, claims that the product "Kills % Germs with the power of/scent of/ fragrance name/scent" are false and misleading. Efficacy of the product is not mediate by the fragrances/scents in the product.
- On pages 23-25, and numerous locations on the proposed label, the terms "deep" and "tough" as descriptors for disinfection/sanitization are unacceptable as they imply heighten efficacy.
- On page 23 of the proposed label, remove the claim "The same ingredient used for disinfecting cuts and scrapes" as it expands the uses to skin.
- Remove all references and iterations of the claims "pure", "biodegradable", "healthy home", "kinder", "friendly", "gloves off", "no gloves needed", and "Fume-Free" as they imply heighten safety and environmental preference
- Remove all references and iterations of "active oxygen", "chlorine free", "bleach free", "oxidation/oxidizing", "no chlorine", "breaks down into/leaves behind only water and oxygen", "non-chlorine", "elements of water and oxygen(?)", and "accelerated/hi-speed hydrogen peroxide", for pesticidal claims.
- On page 28 of the proposed label, remove the claim "Quick easy and convenient disinfecting". The Agency has determined that term "quick" pesticidal claims must demonstrate efficacy in ≤10 seconds.
- On page 28 of the proposed label, the registrant must define the statement "Hygiene beyond cleanliness".
- Allergen claims are limited to non-living allergens with the action of cleaning, removing, or reducing.
- Data Matrix does not indicate MRID numbers for submitted studies and *E. coli* should be changed to *E. coli* O157:H7.